

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election with traverse of Group I, claims 1-15 and species 2, claim 6 in the reply filed on 04 April 2008 is acknowledged.
2. The traversal is on the ground(s) that May does not anticipate claim 1 because May only teaches indicators arranged in series and not in parallel.

This argument is not persuasive. May teaches separate strips or sheets arrange in parallel. See May, page 12, lines 6-20. Claim 1 recites that two different flow tracks are present, yet there is nothing recited in the device of claim 1 that enables this to occur. The only way for two different (independent) flow tracks to be present on the same membrane is for some sort of divider to be present; as such, the divider essentially separate the membrane into separate strips with parallel flow tracks. Furthermore, the recitation of claim 11 implies that there is more than one membrane present, thus implying separate test strips arranged in parallel. Therefore, May anticipates this feature.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 4-5 and 16-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

4. Currently, claims 1-3 and 7-15 are generic. Claims 1-3 and 6-15 are under examination.

*Claim Rejections - 35 USC § 112*

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-3 and 6-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 recites a device comprising "a membrane" with "an application point", a group of "at least two indicator zones", at least one absorption region where the flow directions (of liquid sample) from the application zone through the indicator zones toward the absorption region are parallel and at least two flow tracks are present. However, neither the specification nor claim 1 properly describes how *two parallel* flow tracks can be present on *one* membrane. In order for two flow tracks to be present on the same membrane, there must be some sort of divider or barrier separating them, but neither the claims nor the specification discloses such a feature.

Therefore, claims 1-3 and 6-9 lack proper written description to reasonably convey to one skilled in the art at the time the applicant was filed that applicant had possession of the claimed invention.

*Claim Rejections - 35 USC § 112*

7. Claims 1-3 and 6-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite with respect to the use of parenthetical “flow track”. It is unclear whether the “flow tracks” are positive limitations of the device or whether they are on exemplary matter.

Claim 1 is vague and indefinite because it is unclear how two different flow tracks can be present on only one membrane without any divider or barrier separating them.

Claim 1 is also vague with respect to the recitation of indicator particles that “represents” erythrocytes. It is unclear whether these particles are, in fact, erythrocytes.

Claim 1 is vague with respect to the recitation of "the plasma" which lacks antecedent support.

Claim 1 is also vague because it is unclear if the indicator zones also functions as detection zones. For example, claim 13 recites that the in addition to the indicator zones, the device also comprises a conjugate pad which leads one to surmise that the

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conjugate pad contains labeled binding partners, although this is not recited, and the indicator zones are detection zones. However, the "conjugate" of a label and a binding partner for the analyte is recited as being in the indicator zones. Therefore, the claims are confusing.

Claim 3 is confusing with respect to the description of the indicator zones being arranged in a diagonal V-, W-, M- or N-shaped. It is unclear what this means. Are the zones arranged in the shape of these letters? Do they all have the same indicators?

Claim 11 is vague with respect to the recitation of "all the membranes" since only *one* membrane is recited in claim 1.

Claim 12 is vague with respect to the description of the sealing element. Is this a casing? Does the sealing element cover the entire membrane from the indicator zones forward? What is the purpose of the sealing element?

### *Claim Rejections - 35 USC § 103*

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-3 and 7-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hardman (US 7,303,923) in view of May (WO 88/08534) and Eisinger et al (US 4,943,522).

Hardman discloses a device comprising a porous material, one or more test reagents on the porous material and a transparent water-impermeable coating polymer attached to the porous material so as to define a continuous bibulous compartment. See column 1, lines 39-48. With respect to a device having one application zone, Hardman discloses that there is only one entrance to the bibulous compartment. See column 2, lines 26-27. With respect to a device having at least two indicator zones, Hardman discloses more than one detection reagents may be present to detect a plurality of analytes. See column 4, lines 45-56. With respect to a device having different, parallel flow tracks, Hardman discloses a bibulous compartment comprising a central body with a plurality of channels connected thereto. Detection reagents are provided in each channel. See column 4, line 57 through column 5, line 3, and figures 2 and 3.

Hardman differs from the instant invention in failing to teach at least one absorption region which takes up the liquid after having passed the indicator zones. Hardman also fail to teach reagents specific for blood group antigens.

May discloses a device similar to the instant claims. May teaches an absorbent sink provided at the distal end of a carrier material. The sink can be an additional absorbent paper or a length of the porous solid phase material which extends beyond the detection zone. See page 11, lines 11-17.

Eisinger discloses device and method for detecting blood group antigens. Eisinger teaches reagents for analytes including antigen present on red blood cells. See column 5, lines 37-48. Eisinger teaches methods of blood typing by applying a blood sample to a device having more than one indicator zones, each of which contains a blood typing reagent. See column 5, lines 60-68.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the absorbent sink as taught by May in the device of Hardman because such a feature provides the advantage of the ability to flush away excess fluid from the detection zone thereby preventing back flow and contamination of the detection zone. It also would have been obvious to one of ordinary skill to use the reagents specific to blood group antigens such as taught by Eisinger in the modified device of Hardman because Hardman teaches that their device may be used to detect a variety of analytes and Eisinger teaches that reagents for the detection of blood antigens are well known.

With respect to claim 2, Hardman discloses that the channels are separated by liquid impervious polymers and that the reagents are provided in the channel. Therefore, the test liquid in the different flow tracks does not flow through more than one indicator zones. See column 9, lines 17-22.

With respect to claim 3, May discloses linear rows of indicator zones.

With respect to claim 7, both Hardman and May discloses the use of antibodies and their fragments.

With respect to claim 11, both Hardman and May teaches the use of nitrocellulose membrane.

With respect to claim 12, May and Hardman teaches sealing the membrane with various polymers. See Hardman, column 8, lines 46-64.

With respect to claim 14, May teaches backing the membrane to increase handling strength.

With respect to claim 15, Hardman and May both teaches placing the membrane inside a casing or protective covering. See Hardman, column 2, lines 35-46.

**10.** Claims 1-3 and 7-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klimov et al (US 5,770,458) in view of Eisinger et al (US 4,943,522).

Klimov discloses a device comprising a membrane having an application zone 109, a group of at least two indicator zones 105 (see column 7, lines 46-50), at least one absorption region 111, and at least two flow tracks are present. See column 7, lines 40-44 and 66-67.

Regarding claim 2, Klimov teaches multiple membranes for detecting multiple analytes. See figure 1A and column 10, lines 21-31.

Regarding claim 3, Klimov teaches indicator zones in a linear row. See figure 1D.

Regarding claim 7, Klimov teaches binding reagents comprising antigens or antibodies. See column 7, lines 60-64.

Regarding claim 11, Klimov teaches nitrocellulose membranes. See column 6, lines 51-58.

Regarding claim 12, Klimov teaches that the membrane is disposed in a holder. See column 8, lines 33-34. Klimov also teaches mylar tape 107 between the sample pad and the indicator zone. See column 10, lines 35-38.

Regarding claim 13, when the detection and control zones of Klimov are interpreted as equivalent to the instant indicator zones, then the top membrane holding of labeled reagents are equivalent to the instant conjugate zone.

Regarding claim 14, Klimov teaches backing the membrane for increased handling strength. See column 8, lines 51-53.

Regarding claim 15, Klimov teaches an integrated casing. See column 10, lines 28-30.

Klimov differs from the instant claims in failing to teach indicator particles comprising erythrocytes and binding elements for cellular bound analytes and analytes in plasma.

Eisinger discloses device and method for detecting blood group antigens. Eisinger teaches reagents for analytes including antigen present on red blood cells. See column 5, lines 37-48. Eisinger teaches methods of blood typing by applying a blood sample to a device having more than one indicator zones, each of which contains a blood typing reagent. See column 5, lines 60-68.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Klimov to detect blood group antigens using reagents specific therefor because Klimov teaches that their device is appropriate for a variety of analytes and provides the advantage of a device with uniformed migration of the labeled reagents, eliminating undesirable flooding of the membrane body, and Eisinger teaches reagents and method for blood typing as well known in the art.

**11.** Claims 1-3, 6-11 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kang (US 5,559,041) in view of Eisinger et al (US 4,943,522).

Kang discloses a device for immunoassay comprising a membrane with an application zone 110, at least two indicator zones 218 and 228 (Figure 4), at least one absorption region 116. Kang teaches that the device comprises at least two different tracks and according to figure 3, they may be in different direction. See also column 4, lines 12-65.

Regarding claim 2, Kang teaches multiple flow tracks. See column 4, lines 38-49.

Regarding claim 3, Kang teaches indicator zones arranged linearly. See the figures.

Regarding claim 6, Kang teaches multiple indicator zones arranged opposite each other. See figure 3.

Regarding claim 7, Kang teaches antibodies or antigens as the labeled binding partners. See example 1.

Regarding claim 11, Kang teaches cellulose membrane. See example 1.

Regarding claim 13, Kang teaches conjugate pad comprising labeled reagents. See example 1.

Regarding claim 14, Kang teaches a plastic backing. See column 11, lines 45-53.

Regarding claim 15, Kang teaches a casing. See figure 4.

Kang differs from the instant claims in failing to teach reagents analytes in plasma and cellular bound analyte.

Eisinger is discussed above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Kang to include reagents to detect cellular bound analytes and other in plasma samples because Kang teaches that their device is appropriate for detecting multiples analytes and provide the advantage of a one step device capable of detecting multiple analytes form the same sample with minimal involvement from the user.

### ***Double Patenting***

**12.** The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims

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are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**13.** Claims 1-5 and 7-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 10/563,659 in view of Eisinger et al (US 4,943,522).

'659 teaches a device comprising an application zone, at least one group of at least two indicator zones, at least one absorption region and at least two different flow tracks are present.

'659 differs from the instant claims in failing to teach reagents for the detection of blood group antigens.

See the discussion of Eisinger above.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of '659 to include reagents specific to cellularly bound analytes such as blood group antigens as taught by Eisinger. The device of '659 is generic with respect to the particular analytes and specifically teaches

indicator zones comprising anti-A, B antibodies, etc. and Eisinger teaches that the detection of blood group antigens are well known.

This is a provisional obviousness-type double patenting rejection.

### *Conclusion*

**14.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Monday -- Thursday from 9:00 a.m. - 3:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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